

**DETAILED ACTION**

***Acknowledgement of Applicant's Amendments***

1. The amendments made in claim 1 in the Amendment filed August 8, 2011 have been received and considered by Examiner.
2. New claims 20 and 21 presented in the Amendment filed August 8, 2011 have been received and considered by Examiner.

***Claim Objections***

3. Claims 18 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**WITHDRAWN REJECTIONS**

4. The 35 U.S.C. 112, second paragraph, rejection of claims 10, 11 and 18 have been withdrawn due to Applicant's amendments in claim 1.

**REPEATED REJECTIONS**

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

6. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kishimoto et al. (JP 10-181735) in view of Shinozaki et al. (USPN 6,793,101). JP 10-181735 is cited in IDS and a machine translation is included with this Office Action.

In regard to claim 10, Kishimoto et al. teach a capsule (the container) that consists of cyclic olefin copolymer. See, for example, paragraphs 0015, 0016 and 0018. Eventhough the capsule (the container) is taught as having two layers, the capsule (the container) consists of cyclic olefin copolymer because both layers are cyclic olefin copolymer layers. See, for example, paragraphs 0015, 0016 and 0018 (paragraph 0015 states "...by carrying out orientation relaxation of the cyclic olefin system copolymer of the thin layer of an outside surface", indicating that the outer, thin layer is a cyclic olefin system copolymer layer). The thicker, inner layer is a cyclic olefin copolymer layer because Kishimoto et al. disclose that the "container 1 is formed by the stretch blow molding of the cyclic olefin system copolymer" (paragraph 0016).

In regard to the fluid loss per year property that is not specifically taught by Kishimoto et al., this characteristic would be inherent in the composition: the composition taught by Kishimoto et al. corresponds to the claimed composition, so the skilled artisan would expect the inherent physical characteristics to be the same, as well, since there is nothing otherwise recited that would lead to a different result. Also note that

[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)...

Kishimoto et al. teach that the container includes a cap (paragraph 0016).

While Kishimoto et al. does not specifically teach the material of the cap, Shinozaki et al. teach a bottle comprising a bottle cap sealing unit comprising two separate components (inner cap 2 and outer cap 1) that may comprise a polypropylene resin or a low density polyethylene resin (col. 7, lines 19-21). One of ordinary skill in the art would have recognized to have looked to Shinozaki et al. for a teaching of a particular known material for use as the cap of the container of Kishimoto et al. since both Kishimoto et al. and Shinozaki et al. both pertain to polymeric containers having caps (and since Kishimoto et al. generally teach containers having caps, and do not require a particular structure for the container or cap of the container). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used low density polyethylene as the material of the cap of the container of Kishimoto et al. since low density polyethylene is a known material for producing closures for containers such as caps as taught by Shinozaki et al.

In further regard to claim 10, examiner notes that the recitation regarding the amount of fluid loss per year applies to the cyclic olefin copolymer (or the capsule that consists of the cyclic olefin copolymer), and not to the package as a whole (based on Applicant's claim language, the package includes the cap, the capsule does not include the cap).

In regard to claim 11, Kishimoto et al. and Shinozaki et al. teach the package as discussed above.

While Kishimoto et al. fail to teach that the package further includes a barrier sealing the capsule, Shinozaki et al. teach a barrier (sealing lid 12 which breaks at breaking groove 14 when

the cap is opened) that seals the capsule (that is, the container body) (see, for example, col. 7, lines 36-39 and Fig. 1 and 2). Therefore, since Kishimoto et al. generally teach containers having caps, and do not require a particular structure for the container or cap of the container, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a cap sealing unit including the inner cap having the sealing lid 12 as the cap of the container taught by Kishimoto et al. and Shinozaki et al. in regard to claim 10 when such a structure is desired, depending upon the particular desired end use and characteristics of the container, since the closure structure taught by Shinozaki et al. is a known structure for tamperproof bottles (col. 1, lines 5-11).

### ***NEW REJECTIONS***

#### ***Claim Rejections - 35 USC § 103***

7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieroni et al. (USPN 6,431,350).

Pieroni et al. teach a capsule (container 16) that consists of cyclic olefin copolymer and a cover that is formed of (comprises) a polymeric film such as polyethylene or polypropylene. See, for example, col. 4, lines 1-31, col. 6, lines 21-22 and col. 5, lines 42-45. Pieroni et al. teach that the container holds a dental implant (the polymerizable material) and a fluid suitable for preserving the dental implant (solvent) (col. 4, lines 10-12).

In the instance where Applicant convincingly shows that the polymerizable material specifically disclosed by Pieroni et al. is not a “dental implant” (although the polymerizable material disclosed by Pieroni et al. is considered to be an implant because it is an intermediate

product of the implant in its final implanted [polymerized] form), Pieroni et al. teach that the container may hold a “dental product” (see, for example, col. 3, line 62), and that modifications of the invention that are apparent to one of ordinary skill in the art may be made to the invention that is specifically disclosed (col. 7, lines 42-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have stored a dental implant and a fluid material that is suitable for preserving the dental implant in the container taught by Pieroni et al. since the container of Pieroni et al. is suitable for storing implantable material and a fluid material that is suitable for preserving the implantable material (solvent) as discussed above regarding the polymerizable material and the solvent.

In regard to the fluid loss per year property that is not specifically taught by Pieroni et al., this characteristic would be inherent in the composition: the composition taught by Pieroni et al. corresponds to the claimed composition, so the skilled artisan would expect the inherent physical characteristics to be the same, as well, since there is nothing otherwise recited that would lead to a different result. Also note that

[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.” Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)...

MPEP 2112 I.

While Pieroni et al. do not specifically teach that the polyethylene of the cover is low density polyethylene, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a particular well known polyethylene (such as low density

polyethylene [or high density polyethylene]) as the polyethylene of the cover of Pieroni et al. The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945); *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) (selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious); MPEP 2144.07.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieroni et al. (USPN 6,431,350) in view of Shinozaki et al. (USPN 6,793,101).

Pieroni et al. teach a capsule (container 16) that consists of cyclic olefin copolymer and a cover that is formed of (comprises) a polymeric film such as polyethylene or polypropylene. See, for example, col. 4, lines 1-31, col. 6, lines 21-22 and col. 5, lines 42-45. Pieroni et al. teach that the container holds a dental implant (the polymerizable material) and a fluid suitable for preserving the dental implant (solvent) (col. 4, lines 10-12).

In the instance where Applicant convincingly shows that the polymerizable material specifically disclosed by Pieroni et al. is not a “dental implant” (although the polymerizable material disclosed by Pieroni et al. is considered to be an implant because it is an intermediate product of the implant in its final implanted [polymerized] form), Pieroni et al. teach that the container may hold a “dental product” (see, for example, col. 3, line 62), and that modifications of the invention that are apparent to one of ordinary skill in the art may be made to the invention that is specifically disclosed (col. 7, lines 42-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have stored a dental implant and

a fluid material that is suitable for preserving the dental implant in the container taught by Pieroni et al. since the container of Pieroni et al. is suitable for storing implantable material and a fluid material that is suitable for preserving the implantable material (solvent) as discussed above regarding the polymerizable material and the solvent.

In regard to the fluid loss per year property that is not specifically taught by Pieroni et al., this characteristic would be inherent in the composition: the composition taught by Pieroni et al. corresponds to the claimed composition, so the skilled artisan would expect the inherent physical characteristics to be the same, as well, since there is nothing otherwise recited that would lead to a different result. Also note that

[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)...

MPEP 2112 I.

While Pieroni et al. do not specifically teach that the polyethylene of the cover is low density polyethylene, Shinozaki et al. teach a bottle comprising a bottle cap sealing unit comprising two separate components (inner cap 2 and outer cap 1) that may comprise a polypropylene resin or a low density polyethylene resin (col. 7, lines 19-21). One of ordinary skill in the art would have recognized to have looked to Shinozaki et al. for a teaching of a particular known polyethylene material for use as the cover of the container of Pieroni et al. since both Pieroni et al. and Shinozaki et al. both pertain to polymeric containers having covers. It would have been obvious to one of ordinary skill in the art at the time the invention was made

to have used low density polyethylene as the material of the cover of the container of Pieroni et al. since low density polyethylene is a known material for producing closures for containers taught by Shinozaki et al.

***Response to Arguments***

9. Applicant's arguments in regard to the 35 U.S.C. 103 rejection of claims 10 and 11 as being unpatentable over Kishimoto et al. (JP 10-181735) in view of Shinozaki et al. (USPN 6,793,101) have been fully considered but are not persuasive.

On page 5 of the Amendment filed August 8, 2011, Applicant states that "Applicant has discovered that a LDPE cap in combination with a COC capsule is particularly advantageous for preserving a dental implant in the fluid material...". Applicant characterizes this discovery as "provid[ing] a synergistic result, which goes beyond the sum of its parts". Page 5 of the Amendment filed August 8, 2011.

This allegation of "a synergistic result, which goes beyond the sum of its parts" is an allegation of unexpected results (synergism, "which goes beyond the sum of its parts"). An allegation of unexpected results must be supported by evidence. MPEP 716.02. Applicant has not provided any evidence in the specification or otherwise that supports Applicant's allegation of a synergistic result. Applicant states on page 5 of the specification that HDPE and LDPE is "particularly advantageous", but this is not a showing of "a synergistic result, which goes beyond the sum of its parts". The arguments of counsel cannot take the place of evidence in the record. MPEP 2145 I.



Examiner notes that Fig. 2 of Applicant's specification does not make a showing of a synergistic result because (1) it does not provide data for material combinations for cap and capsule combinations (one data point for each combination of material for cap and capsule is not shown) and (2) it does not appear to provide any data for the property that is alleged to be unexpectedly high in Applicant's argument (preserving ability ["particularly advantageous for preserving a dental implant in the fluid material"; page 5 of Amdt.] and seal ability ["liquid tight seal"; page 5 of Amdt.]).

Examiner notes that the data in Fig. 2 tends to show that the use of LDPE for the cap with COC for the capsule would not be advantageous over the other cap materials shown in Fig. 2. If the oxygen and water vapor permeability data is considered, Fig. 2 shows that LDPE as the cap material is the most permeable to water vapor and oxygen when compared to the other cap materials (PP and HDPE). This would tend to indicate that LDPE does not achieve better sealing effect over polypropylene, or over another polyethylene (HDPE). If there is a synergistic effect achieved from this combination of COC for the capsule and LDPE for the cap, Applicant has not provided any evidence that shows this. Fig. 2 does not show or even hint at any evidence of this (and Fig. 2 suggests the opposite: that LDPE would not be the material to choose for the cap to have maximum preserving ability and/or seal ability). Again Examiner notes that the specification does not appear to provide any data for the property that is alleged to be unexpectedly superior in Applicant's argument because data for preserving ability and seal ability for the possible combinations of materials are not shown. If oxygen and/or water vapor permeability are taken as an indicator of preserving ability (or seal ability), the data in Fig. 2 tends to show that LDPE for the cap material would achieve worse results than HDPE or PP.

What results would actually be achieved by each possible combination is not reported anywhere in Applicant's specification or elsewhere, so Applicant has provided no showing of synergistic results from the combination of COC for the capsule and LDPE for the cap. The arguments of counsel cannot take the place of evidence in the record. MPEP 2145 I.

Examiner notes that there is no mixing of chemical compounds involved in this application (sometimes a mixing of chemical compounds results in a composition that achieves unexpected [synergistic] results over what would be achieved with solely one of those compounds). If LDPE is inferior in permeability values as compared to HDPE and PP (as indicated in Fig. 2), it would be expected that a COC container having an LDPE cap would be inferior in permeability values as compared to COC containers having either HDPE or PP caps.

Applicant argues on page 6 of the Amdt. that one of ordinary skill in the art would not necessarily choose LDPE for the material of the cap of the COC container of Kishimoto et al. However, one of ordinary skill in the art would have been guided to choose LDPE from a finite list of materials for the cap since Shinozaki et al. establish that LDPE is a well known material for caps. Examiner notes that Shinozaki et al. require that both parts of the cap are made from either PP or LDPE. Col. 7, lines 19-21.

Applicant argues in the paragraph bridging pages 6 and 7 that the goal of Kishimoto et al. is different from the goal of Applicant and that Kishimoto et al. do not disclose that COC is "particularly beneficial for the storage of any particular substance or object", but Kishimoto et al. need not disclose either of these things: Kishimoto et al. teach a COC container. Claim 10 does not require that the container store anything in particular ("for holding a dental implant and for containing a fluid material suitable for preserving the dental implant"). Kishimoto et al. teach a

COC container, so the container is capable of holding a dental implant and containing a fluid material suitable for preserving the dental implant. Note that:

the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.

MPEP 2144 IV.

Applicant argues on page 7 that “no particular benefit or advantage of LDPE is disclosed by Shinozaki et al.”. However, Shinozaki et al. need not show or suggest any particular benefit or advantage of LDPE. Shinozaki et al. establish that LDPE is a well known material for caps. The fact that “no particular benefit or advantage of LDPE is disclosed by Shinozaki et al.” tends to indicate that LDPE is simply a well known material for use as a cap of containers. Therefore, one of ordinary skill in the art would have recognized to have used LDPE as the material of the cap of the container of Kishimoto et al. since LDPE is a well known material for use as a cap of containers.

Applicant argues in the paragraph bridging pages 7 and 8 that there is no teaching or suggestion in either reference to use COC as the container material with LDPE as the cap material, but as discussed above, one of ordinary skill in the art would have been guided to choose LDPE from a finite list of materials for the cap since Shinozaki et al. establish that LDPE is a well known material for caps.

Applicant mentions again on page 8 the alleged synergistic results achieved by the combination of COC as the container material with LDPE as the cap, but, as discussed above, there is no actual showing of these synergistic results, and the data that is presented in the

specification calls into question whether or not synergistic results (which are better than the other possible combinations disclosed in the specification) would be achieved (as also discussed above). Examiner notes that there is no mixing of chemical compounds involved in this application (sometimes a mixing of chemical compounds results in a composition that achieves unexpected [synergistic] results over what would be achieved with solely one of those compounds). If LDPE is inferior in permeability values as compared to HDPE and PP (as indicated in Fig. 2), it would be expected that a COC container having an LDPE cap would be inferior in permeability values as compared to COC containers having either HDPE or PP caps.

Applicant argues on page 8 that the cap of Shinozaki et al. has particular structural features that are different (and more complex [the cap comprises inner and outer caps]) than the simple cap of Kishimoto et al., but Shinozaki et al. is relied upon to establish that LDPE is a well known material for caps. If LDPE is suitable for the more complex cap of Shinozaki et al., one of ordinary skill in the art would have recognized to have used LDPE for the more simple cap of Kishimoto et al. (since Shinozaki et al. establishes that LDPE is a well known material for caps). Examiner notes that Applicant admits that “both parts of the cap [of Shinozaki et al.] can be made from a synthetic resin, such as LDPE”. Page 7 of Amdt. Examiner further notes that Shinozaki et al. require that both parts of the cap are made from either PP or LDPE. Col. 7, lines 19-21.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 7:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/WALTER B AUGHENBAUGH/

Primary Examiner, Art Unit 1782

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